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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/823,691

04/14/2004

Steven J. Soldin

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EXAMINER

WALLENHORST, MAUREEN

ART UNIT

PAPER NUMBER

1797

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DELIVERY MODE

04/18/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/823,691	Applicant(s) SOLDIN, STEVEN J.	
	Examiner Maureen M. Wallenhorst	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 March 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18,21-27 and 34 is/are rejected.
- 7) ☒ Claim(s) 1-34 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 5, 2008 has been entered.

2. Claims 1-34 are objected to because of the following informalities: In claims 1, 27, 28, 30, 32 and 34, the phrase "or suspected of containing" is objected to since if the sample analyzed is only suspected of containing a multitude of steroid hormones but does not actually contain a multitude of steroid hormones, then the step of analyzing the multitude of steroid hormones by a mass spectrometer would not occur, and the method would not make proper sense. It is requested that this phrase be deleted from claims 1, 27, 28, 30, 32 and 34. In claim 2, the phrase "wherein the multitude of steroid hormones are selected from the group consisting of cortisol, 11-deoxycortisol, androstenedione, 17-OH progesterone, progesterone, allopregnanolone, and" should be deleted since this phrase no longer makes proper sense with the amendment made to claim 2 in the response received March 5, 2008. Appropriate correction is required.

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference

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claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1-18 and 21-27 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 28, 30-36, 38-55 and 57 of copending Application No. 10/823,690. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims recite a method for mass spectrometric analysis of a sample containing one or more steroid hormones comprising the steps of providing a sample containing one or more steroid hormones, deproteinating the sample, separating the one or more steroid hormones from the sample, and analyzing the one or more steroid hormones using a mass spectrometer, wherein the one or more steroid hormones are selected from the group consisting of testosterone, aldosterone, dehydroepicandrosterone, dehydroepiandrosterone sulphate (DHEAs), and estrogens such as estradiol, estrone, etc. Since the phrase "one or more steroid hormones" recited in the claims of application serial no. 10/823,690 includes "at least four hormones" as recited in the instant claims, claims 28, 30-36,

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38-55 and 57 of application serial no. 10/823,690 are not patentably distinct from claims 1-18 and 21-27 of the instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Alary (article submitted in the IDS filed on November 30, 2006) in view of Draisci et al (article from Journal of Chromatography A).

Alary teaches that multiple steroid compounds in a sample can be advantageously analyzed using LC-MS/MS analysis equipped with an atmospheric pressure photoionization source. A multitude of steroid hormones including testosterone and ethynyl estradiol (an estrogen hormone) are analyzed on an API 3000 LC/MS/MS system having a photoionization source. Alary teaches that the photoionization source produces enhanced and improved signals

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over those obtained using a conventional atmospheric pressure chemical ionization source (APCI). See the entire Alary article. Therefore, Alary teaches of a method comprising the steps of providing a sample containing a multitude of steroid hormones, and analyzing the steroid hormones using a mass spectrometer, wherein the multitude of steroid hormones comprises at least one estrogen (i.e. ethynyl estradiol). Alary fails to teach that the sample is deproteinated and thereafter, the steroid hormones are separated from the sample prior to analysis by mass spectrometry.

Draisci et al teach of a method for the quantitation of the steroid hormones 17-beta-19-nortestosterone, 17-beta-testosterone and progesterone in a blood serum/plasma or urine sample by the use of liquid chromatography-tandem mass spectrometry. In the method, a 2 mL sample of blood serum/plasma or urine is obtained that contains the hormones 17-beta-19-nortestosterone, 17-beta-testosterone and progesterone, the sample is deproteinated and purified by solid phase extraction using a C-18 cartridge, eluted with methanol, and injected into a LC-MS-MS system. An injection valve equipped with a 5 microliter internal loop is used for injection of the sample into the LC-MS-MS system. The steroid hormones are separated from the sample by the liquid chromatography step, and analyzed using the mass spectrometer. The mass spectral analysis is performed on a mass spectrometer operating in the positive ion mode that is equipped with an atmospheric pressure chemical ionization (APCI) source. Draisci et al teach that the combination of liquid chromatography with tandem MS-MS offers a rapid, simplified and sensitive method for analyzing a multitude of steroid hormones in a blood serum/plasma or urine sample that involves simple extraction procedures and removes the need for derivatization reactions. See pages 511-513 in Draisci et al.

Based upon the combination of Alary and Draisci et al, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to deproteinate the sample containing a multitude of steroid hormones including at least one estrogen taught by Alary and separate the resulting steroid hormones prior to analysis by mass spectrometry since Draisci et al teach that it is advantageous to deproteinate a sample containing multiple steroid hormones and separate the resulting hormones from the sample prior to analysis by mass spectrometry in order to remove proteins from the sample that may interfere with the mass spectral analysis and provide a purified sample to the mass spectrometer.

8. Applicant's arguments filed March 5, 2008 have been fully considered but they are not persuasive.

The previous objections to the abstract and claims in the last Office action mailed on December 5, 2007 have been withdrawn in view of the amendments made to the abstract and claims. However, new objections to the claims have been made herein, as noted above. The previous rejections of the claims under 35 USC 102 as being anticipated by Draisci et al and Tiller et al have been withdrawn in view of Applicant's amendments to the claims. In addition, the previous rejections of the claims under 35 USC 103 as being obvious over Draisci et al or Tiller et al in view of Jonsson et al, over Draisci et al or Tiller et al in view of Vogeser et al, over Draisci et al or Tiller et al in view of Alary, over Draisci et al or Tiller et al in view of Fredline et al, and over either Draisci et al or Tiller et al have been withdrawn in view of Applicant's amendments to the claims. Therefore, Applicant's arguments regarding these rejections will not be addressed.

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Applicant is informed that in order to place the instant application in condition for allowance, the claims should be amended as suggested in the objection to the claims, as set forth above, a terminal disclaimer should be filed over application serial no. 10/823,690, and claim 34 should be canceled.

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9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen M. Wallenhorst whose telephone number is 571-272-1266. The examiner can normally be reached on Monday-Thursday from 6:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maureen M. Wallenhorst
Primary Examiner
Art Unit 1797

mmw

April 15, 2008

/Maureen M. Wallenhorst/

Primary Examiner, Art Unit 1797

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